

METHOD FOR TREATING GINGIVAL AND PERIODONTAL TISSUES

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention concerns a method for treating gingival and periodontal tissues.

2. The Related Art

The importance of maintaining proper gingival and periodontal health has been well established. The factors normally evaluated in determining the health of a patient's periodontium are the following:

- (1) gingival tone, texture and consistency;
- (2) gingival attachment as measured in the sulcus (6 reference points about each tooth) with a calibrated periodontal probe;
- (3) gingival enlargement;
- (4) gingival bleeding when provoked by instrumentation (amount and length of time of bleeding);
- (5) the presence of chronic destructive periodontal disease which, if advanced, will threaten loss of dentition, i.e. severe bone loss, tooth mobility, deep pocket formation, bleeding, etc.;
- (6) the presence of pain or discomfort to the patient.

Treatment of the foregoing may comprise regular and periodic massaging of the gingivae, tooth brushing and rinsing of the mouth on a regular basis, deep scaling and curettage procedures performed by dentists, bacterial control and in extreme cases, surgical procedures may become necessary.

Oral compositions containing both a peroxide and sodium bicarbonate have been reported as excellent curative and preventative systems against gum disease. Dr. Paul H. Keyes has long advocated use of such systems to the dental profession and to the public at large. For instance, see Keyes et al. "Periodontics and Oral Hygiene", January 1978, pages 51-56. Formulations based on the Keyes technology, especially the peroxide component, are particularly prone to decomposition. A quite successful approach to the decomposition problem has involved physical separation of the peroxide into a compartment separate from co-reactive ingredients. U.S. Pat. Nos. 4,849,213, 4,687,663 and 4,528,180, all to Schaeffer, disclose packages with a dual compartment respectively storing a peroxide and a bicarbonate composition. Improvements in this technology have been reported in U.S. Pat. Nos. 5,037,633, 5,037,634, 5,059,417, 5,085,853 and 5,217,710 all having inventorship by Williams and coworkers.

In U.S. Pat. Nos. 4,788,052, 4,839,156 and 4,839,157 (all to Ng et al) are described aqueous hydrogen peroxide gel dentifrices that can be stabilized by use of a combination of hydrophilic and hydrophobic fumed silica.

Aqueous mouthrinses have been described in U.S. Pat. No. 5,104,644 (Douglas) that contain hydrogen peroxide. Present at relatively low concentrations are also such additives as zinc chloride, surfactant, sodium citrate and citric acid. Hydrogen peroxide is stated to function as the principal active ingredient against anaerobic organisms and to assist removing microbiota through the mechanical actions of bubbling and foaming. Zinc chloride is incorporated for the stated purpose of astringency in combination with the peroxide to help edematous gingiva return to a more normal state. Sodium citrate is present for the stated purpose of being an anticoagulant for healing hemorrhagic tissue. Lev-

els of zinc chloride in these compositions range from 0.02% to 0.8% by weight.

Control of gingivitis has also been reported in U.S. Pat. No. 4,575,457 (Mazarin) through use of a composition containing a skin respiratory factor (SRF) along with sodium chloride, bicarbonate, fluoride and zinc chloride.

Germicidal effects of hydrogen peroxide in combination with zinc salts have been reported in U.S. Pat. No. 4,557,935 (Af Ekenstam et al.). Combinations of zinc and peroxide have also been reported in U.S. Pat. No. 4,477,438 (Wilcoxon et al.) and in a series of patents to Vlock, namely U.S. Pat. Nos. 4,937,066, 5,094,845 and 4,165,914.

As seen from the aforementioned list of references, there has been considerable progress in the art. However, none of these described systems have been fully effective against gingival and periodontal problems while being both safe and aesthetically consumer acceptable.

Accordingly, it is an object of the present invention to provide a method for the treatment of gingival and periodontal disease.

It is another object of the present invention to provide a method for preventing gingival bleeding, gum recession and loss of gingival tone, texture or consistency.

It is still another object of the present invention to provide a method for the treatment and prevention of gum disease that does not stain teeth, contains no chlorinated actives and in all ways is safe and effective.

It is a still further object of the present invention to provide a method for the treatment and prevention of gum disease through use of a composition that not only is effective but also minimizes taste problems often associated with astringent materials.

These and other objects of the present invention will become more readily apparent upon consideration of the more detailed description and Examples which follow.

SUMMARY OF THE INVENTION

A method is reported for inhibiting gingival bleeding and improving texture and consistency of gingival and periodontal tissues in a procedure which includes:

- (i) delivering a first composition to a receptacle such as an expectorant cup or toothbrush, the first composition comprising from about 0.1 to about 10% by weight of zinc salt in a pharmaceutically acceptable carrier;
- (ii) delivering a second composition to the receptacle, the second composition comprising from about 1 to about 80% by weight of a bicarbonate salt in a pharmaceutically acceptable carrier;
- (iii) transferring from the receptacle into the mouth a combination of the first and second compositions within five minutes of their delivery to the receptacle; and
- (iv) agitating the combination of first and second compositions within the mouth against the gingival and periodontal tissues.

Also reported is a method for inhibiting gingival bleeding and improving the texture and consistency of gingival and periodontal tissues in a procedure which includes:

- (i) extruding a first composition onto a toothbrush, the first composition comprising from about 0.1 to about 10% by weight of zinc salt in a pharmaceutically acceptable carrier;
- (ii) extruding a second composition onto the toothbrush comprising from about 1 to about 80% by weight of a bicarbonate salt in a pharmaceutically acceptable carrier; and